COOLRENEWAL
www.cool-renewal.com

Cool Renewal®
Cryosurgical Spray

Instructions for Use

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Read all instructions prior to use.

Cool Renewal, LLC
3/1/2022

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Caution: Federal law restricts this device to sale by or on the order of a physician, veterinarian, or dentist.

Cryosurgery Introduction

Thank you for choosing Cool Renewal® Cryosurgical Spray. Cool Renewal® is a portable, hand held cryosurgical device which contains a non-flammable refrigerated gas, with an ideal formulation for cryosurgical procedures.

Even if this is your first time purchasing a cryosurgical unit, most physicians and medical professionals have had some exposure to cryosurgical techniques during medical school, residencies, or continuing education seminars. This short review of the science of cryosurgery will provide more insight to the science of the procedure and expectations.

Cryosurgery (also called cryotherapy) is the use of extreme cold to destroy abnormal tissue. Cryosurgical procedures have been used in practices for over 100 years, and the clinical applications are continuously increasing and improving. Cryosurgery now has a wide range of clinical applications: dermatology, gynecology, urology, pulmonary medicine, cardiology, pediatrics, oncology and many others. It is also used in veterinary medicine. With appropriate instruction and supervised experience, medical professionals can master the technique quickly. Cryosurgery requires little time and fits easily into the physician's office schedule. Advantages of this treatment include a short preparation time, low risk of infection, and minimal wound care. In addition, cryosurgery requires no expensive supplies or injectable anesthesia, and the patient does not have to return for suture removal. Since cryosurgery is a bloodless procedure, it is a great alternative to scalpel or laser treatments which involve exposure to blood born infectious diseases, such as those caused by HIV and Hepatitis B.

Liquid nitrogen, which boils at −196°C (−320.8°F), is the most commonly used cryogen for clinical use, however, generally, destruction of external benign lesions only requires temperatures of −20°C to −30°C (−4°F to −22°F). Cool Renewal™ freezes down to -70°C, which is ideal for causing tissue destruction with prolonged exposure, but still gentle enough to minimize the chance of scarring, as compared to liquid nitrogen which can be extremely dangerous if not used properly.

Mechanisms of injury are the direct effects of freezing on the cells and the vascular stasis which develops in the tissue after thawing. The damaging effects of low temperature on cells begin gradually as temperature drops. Cell metabolism and structure are altered along with their constituent proteins and lipids. As the temperature falls to below 0°C, water crystallizes, which results in more damage than from mere prolonged cooling, forming an "ice ball". During cryosurgery, both extracellular and intracellular ice formation occur, with fast freezing in the center of the lesion, and slow freezing on the outside border. The loss of blood supply eradicates the likelihood of survival of the cells in the frozen tissue. The degree of damage depends on the rate of cooling and the minimum temperature achieved. Inflammation develops during the 24 hours after treatment, further contributing to destruction of the lesion through immunologically mediated mechanisms. If the freeze time or the thaw time is too short, tissue destruction will not occur.

When using cryosurgery, achieving maximum results will develop over time with practice and familiarity with the freeze/thaw procedures and results. When used properly, as with any medical device, cryosurgery techniques can prove to be a valuable therapeutic technique. Physicians/medical professionals and patients must work together and share the responsibility of proper use and desired results.

Formal cryosurgery training is available through the National Procedures Institute's Dermatologic Procedure's course. http://www.npinstitute.com/product-p/dermatologic-procedures.htm National Procedures Institute

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Additional Cryosurgical References

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Instructions for Use

Indications for Use

1,1,1,2-Tetrafluoroethane (R-134a), 2,3,3,3-Tetrafluoropropene (R-1234yf), Pentafluoroethane (R-125), Difluoromethane (R-32) is to be used for the treatment of verruca (warts) including plantar warts, seborrheic keratosis, actinic keratosis, achrochordon, molluscum contagiosum, age spots, dermatofibroma, small keloids, granuloma annulare, porokeratosis plantaris, angiomas, keratoacan-thoma, chondrodermatitis, epithelial nevus, leukoplakia, granuloma pyogenicum, and pyogenic granuloma.

Contraindications

- Cool Renewal® should be used only on benign lesions. Do not treat lesion if cancer is suspected; if there is doubt that a lesion is benign, it should first be biopsied.
- Not recommended for those with diabetes and others with poor circulation, as healing time is considerably slower.
- Do not use on irritated or infected skin. Do not use on bleeding, open or breached lesions. Do not use on mucus membrane areas.
- Not recommended for use in treatment of children under the age of 5 years. (Inamadar, Palit, & Ragunatha, 2011) Topical anesthetics are useful when treating children (Cryosurgery for Warts, 2015) (Preoperative Care for Cryosurgery, 2015)

Warnings

Read all instructions prior to use. Raw meat or wax may be used for practicing with the plastic funnels prior to patient use.

Exam gloves should be worn to protect the user from the cryogenic agent.

Use cryogen in a well-ventilated area.

NEVER ATTEMPT TO OPEN SPRAY CRYOGEN ONTO A LESION WITHOUT THE USE OF A

RECOMMENDED AND APPROVED COOL RENEWAL® APPLICATOR. Failure to use an applicator and attempt an open spray could result in damage of surrounding healthy tissue. Cool Renewal® cannot guarantee results with unapproved applicators, which are not manufactured and distributed by Cool Renewal, LLC.

Do not attempt facial treatments until you have substantial experience and are familiar with the applicators and recommended treatment times.

Do not treat areas that cannot be diagnosed with certainty. If you are unsure of the lesion classification, a biopsy can be performed prior to treatment to determine classification and if cryosurgery with Cool Renewal® is a treatment option.

When treating sensitive areas of the body such as around the eyes and ears, be sure to shield or protect the areas so that the cryogen does not come into contact with healthy tissue.

Never freeze scrotum tissue with testicle directly beneath. Always gently separate scrotum tissue that is being treated away from the testicle, then perform the procedure.

Never use plastic funnels to treat lesions on the head, face or neck. There could be occasional splatter when using the funnels, so foam tipped applicators should be used to control the cryogen application in sensitive and bony areas.

Always position the patient properly when using the plastic funnels. The funnel should be perpendicular to the ground, allowing for accumulation of cryogen. If patient cannot be positioned for cryogen accumulation within the plastic funnel, a foam tipped applicator should be used.

Shield the patient's eyes with eye shields and ear canals with ear plugs to prevent any drainage or leakage into those areas when treating lesions around the Patient's eyes or ears. Position the patient so the foam tip is below the eye or ear structure or so it is not possible for a drop of cryogen to drain in the direction of the eye or ear structure.

Treat patients who have heavily pigmented skin, sensory loss, poor blood supply, children and /or the elderly with caution. It is not recommended for use with children under the age of 5 years. Those with collagen vascular disease, cryoglobulinemia, diabetes, stasis problems, pyoderma gangrenosum and ulcerative bowel disorders may present special problems. Physician's discretion should be used for patient selection.

Do not attempt to clean Cool Renewal® applicators. ALL Cool Renewal® applicators are DISPOSABLE. Applicators may be used multiple times on the same patient, but should be disposed of between patients to avoid spreading potential bacteria, diseases, viruses, etc.

There is a safety release valve on the bottom of the canister. Should cryogen ever release from this valve while in use, immediately protect the patient and yourself by promptly removing the canister or people from the area. Allow contents to discharge in a safe area, and contact Cool Renewal, LLC.

Cautions

Do not puncture or incinerate canister. DO NOT attempt to refill an empty canister. Federal law prohibits transportation if refilled and a penalty of up to $500,000 fine and 5 years imprisonment (49 USC 5124).

If the canister is dropped, inspect for damage to nozzle or leakage. Damage may not be visible and practitioner may not know if the canister was dropped since it was last used. If the trigger nozzle is cracked- DO NOT USE. If you can see the clear tube behind the white trigger (inside the nozzle housing) is bent- DO NOT USE- Contact Cool Renewal, LLC for a replacement.

Plastic funnels should NEVER be used on the head, face or neck, or any area where a tight seal is not possible.

Always use gentle pressure when activating the trigger nozzle. This will reduce cryogen waste and prevent splatter when using the plastic funnels. Reducing waste means more treatments per canister! Human patients and animals can be startled from too much pressure applied to the trigger. To gain confidence in gauging the appropriate pressure, point the canister towards the ground, away from patients/persons/animals, and gently apply pressure until you are comfortable with the control.

For thin skin or sensitive areas, it is recommend to under-treat the patient and follow up within 14 days for a retreatment if necessary.

DO NOT TOUCH the lesion for at least 40 seconds after the procedure. Allow the lesions to thaw naturally. Early thawing will reduce the effectiveness of the freeze and lesion destruction.

Do not use lubricants such as petroleum jelly. This will interfere with the freeze/thaw cycles.

If lesions persist post-treatment, lesions should be re-inspected and confirmed that lesions are not cancerous.

Unless you are experienced, it is not recommended to treat more than 3 lesions per patient per visit. Multiple treatments can be stressful or traumatic for the patient, but the exact number depends on patient tolerance and the degree of confidence and skill of each medical professional.

Potential Complications of Cryosurgery

- One must distinguish benign from malignant lesions; biopsy for diagnosis prior to treatment if in doubt.
- Acute reactions may involve pain, inflammation, hemorrhage and systemic effects although all are usually mild and self-limiting, if they occur.
- The most common long term effects include pseudoepitheliomatous hyperplasia, milia formation, nerve damage (usually temporary), pigment issues (usually temporary), tissue defects, and occasional reoccurrence. Many of these problems are due to lack of skill, experience and judgment of the physician performing the cryosurgical treatment.
- **Short-term complications** involve delayed bleeding, infections and granuloma pyogenicum. These are relatively rare. Rare reports of infection appear to be mostly in hot and humid or tropical regions of the world.
- Safety in pregnancy has not been established.

Personal Protection

Exam gloves should be worn to protect the user from the cryogenic agent. Thin cotton surgical glove liners can be used under gloves to keep hands warm. Be extremely careful to protect the patient's ears and the patient's eyes with eye protectors when working around the patient's face. Ophthalmologists use eye spoons to protect the patient's eyes when treating near the eyes or on eyelids. Use of Foam Tipped Applicators is recommended on head, face, and neck.

Component Identification

- Cool Renewal® canister(s) of cryogen
- Extender Tube
- Instructions for Use
- Disposable Foam Tipped Applicators
  - Small, round and pointed tips
  - Medium, round and pointed tips
  - Large/Extra Large, round tips
- Disposable Isolation funnels
  - (5mm)
  - (8mm)
  - (12mm)
  - (14mm)
  - (16mm)
- Skin Tag Tweezers
- Patient Instruction Tear Pad
- Applicator Practice Pad

Choosing an Applicator

Select an applicator based on the size and location of the lesion being treated. Foam Tipped Applicators should be used on the head, neck, bony surfaces, or hard to reach areas. Isolation Funnels should be used on fleshy tissue areas where a tight seal can be achieved, and should not be used on the head, neck, bony surfaces, or heard to reach areas. Skin Tag Tweezers may be used on pedunculated lesions.

Applicator Type	Applicator Size	Lesion Size Range
Foam Tipped Applicator	Small Pointed	1-2 mm
Foam Tipped Applicator	Small Round	4-5 mm
Foam Tipped Applicator	Medium Pointed	4-5 mm
Foam Tipped Applicator	Medium Round	6-7 mm
Foam Tipped Applicator	Large Round	9-10 mm
Foam Tipped Applicator	Extra Large Round	11-12 mm
Isolation Funnel	5mm	4-5 mm
Isolation Funnel	8mm	7-8 mm
Isolation Funnel	12mm	11-12 mm
Isolation Funnel	14mm	13-14 mm
Isolation Funnel	16mm	15-16 mm
Skin Tag Tweezers	One Size	*May be inverted to treat 25 mm lesions Base of Stalk: 1mm- 5mm Length of Stalk: 1mm-10mm

Directions For Use

(See Applicator Detail Flow Chart)

Upon receiving your Cool Renewal® Kit or Replacement Canister, always be sure to inspect your canister for damages prior to usage. Remember damage may not be visible and the practitioner may not know if the canister was dropped since it was last used. If the trigger nozzle is cracked - DO NOT USE - If you can see the clear tube located behind white trigger (inside the white nozzle housing) is bent - DO NOT USE - contact Cool Renewal, LLC.

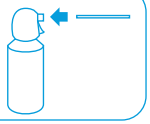
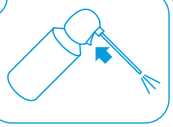
Test the spray by inserting the extender tube (Canister Preparation in flow chart) pointing the canister toward the floor and gently pulling the trigger. Cryogen should spray from the end of the extender tube in a light mist or stream. If cryogen does not come out, refer to the "Frequently Asked Questions" section of this manual.

Step 1: Remove the safety tab on the top of the trigger nozzle and firmly insert the extender tube into the canister's nozzle. **(See Image 1 in Flow Chart)**

Step 2: Test the canister by pointing the extender tube towards the ground and gently pulling the trigger to ensure the extender tube is secured. **(See Image 2 in Flow Chart)**

Step 3: Select an applicator based on the size and location and thickness of the lesion being treated. To ensure the entire lesion will be treated, the applicator chosen should be approximately 1mm greater than the lesion. Foam Tipped Applicators are convenient when treating bony surfaces or hard to reach areas of the body (knuckles, between fingers and toes, helix of the ear, head and neck). Plastic Isolation funnels are convenient for treating fleshy tissue areas of the body (excluding the head and neck) where a tight seal can be achieved (back, bottom of foot, forearm). Skin Tag Tweezers are convenient when treating skin tags (achrochordon) or pedunculated lesions, commonly appearing in the neck, armpit and groin areas of the body. Follow instructions for the applicator selected. **(See flow chart for step-by step instructions for each applicator)**

Canister Preparation

1. 
   Remove safety tab on top of the trigger nozzle labeled "TEAR OFF TAB". Firmly insert the extender tube into the canister's nozzle, as shown.
2. 
   Test the canister by pointing the extender tube towards the ground and gently pulling the trigger to ensure the extender tube is secured.
3. Select an applicator based on the size and location of the lesion being treated. To ensure the entire lesion will be treated, the applicator chosen should be approximately 1mm greater than the lesion.

Foam Tipped Applicator Use

1. 
   Point the extender tube and the cryogen towards the selected foam tip of the applicator, apply gentle pressure to the trigger releasing the cryogen. Foam Tip may be rotated during spray to ensure maximum saturation. The foam tip should drip at least once.
2. 

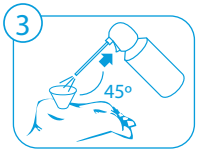
   Holding the applicator with the foam tip towards the ground, wait approximately 15 seconds for the foam tip to crystalize, allowing the refrigerant temperature to drop for maximum effectiveness.
3. 
   Place the frozen applicator directly onto the skin lesion and hold in place for the suggested freeze time outlined in the "Recommended Freeze Time" section of this instruction manual.
4. 
   Once the suggested freeze time is complete, remove the applicator and a white ice ball will appear on top of the lesion. If an ice ball does not appear, either the treatment time was not long enough or the foam tipped applicator was not completely saturated.
5. 
   The treatment will need to be repeated if an ice ball does not appear after application.
6. 

   The ice ball will need to thaw naturally for a minimum of 40 seconds. Premature warming of cells will minimize the effectiveness of the freeze, and the procedure will need to be repeated.
7. 
   Dispose of the applicator when all treatments per patient are complete. Do not use on multiple patients.

Isolation Funnel Applicator Use

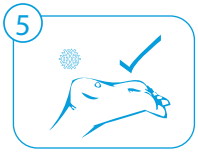
1. 
   Choose a funnel that is approximately 1mm greater than the skin lesion being treated, to ensure the entire lesion is being treated and to minimize chances of reoccurrence.

2. 
   Place the small end of the funnel over the skin lesion and press down to create a seal around the skin lesion. Be sure the funnel is positioned perpendicular to the ground to allow for accumulation of cryogen inside the funnel.

3. 

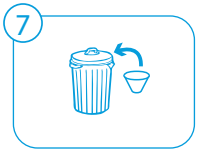
   While holding the funnel in place with one hand, use the other hand to apply pressure to the trigger on the canister, directing the extender tube to the inside wall of the plastic funnel. Gently spray cryogen at a 45° angle against the inside wall of the funnel for approximately 3 – 6 seconds, allowing the cryogen to drip down onto the lesion and accumulate. Accumulation should be at least 1/4 inch of cryogen on top of the skin lesion. Too much trigger pressure or spraying directly onto the lesion may cause splatter.

4. 
   Hold the funnel in place until all of the cryogen inside has completely evaporated. This should take 20-40 seconds, depending on the size of funnel used. If the funnel is removed before the cryogen has evaporated, the cryogen will spill onto healthy surrounding tissue. If you feel too much cryogen was used, a foam tipped applicator can be placed inside the cone to absorb the excess cryogen.

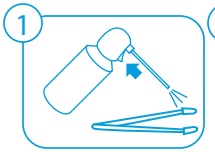
5. 
   Once the cryogen has completely evaporated, the funnel is removed to reveal an ice ball formation on the skin lesion. If an ice ball does not appear, too little cryogen was used and the treatment will need to be repeated using more cryogen.

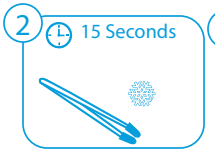
6. 

   The ice ball will need to thaw naturally for a minimum of 40 seconds. Premature warming of cells will minimize the effectiveness of the freeze, and the procedure will need to be repeated.

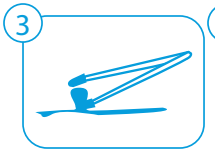
7. 
   Dispose of the applicator when all treatments per patient are complete. Do not use on multiple patients.

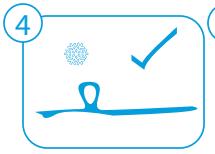
Skin Tag Tweezer Applicator Use

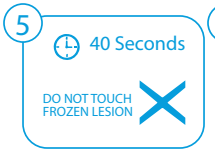
1. 
   Point the extender tube and the cryogen towards the foam tips of the tweezers, apply gentle pressure to the trigger releasing the cryogen, and continue to spray each foam tip interior for 3-5 seconds, ensuring complete saturation. Spraying primarily towards the interior portions of foam is desirable, as this is the portion that will be in direct contact with the skin tag.

2. 

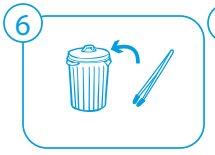
   Holding the applicator with the foam tips towards the ground, wait approximately 15 seconds for the foam tip to crystalize, allowing the refrigerant temperature to drop for maximum effectiveness.

3. 
   Position the tweezers over the skin tag, squeeze the foam tips together and press down towards the base of the skin tag, being sure to freeze the base for the recommended freeze time.

4. 
   Once the suggested freeze time is complete, remove the applicator and an ice ball will appear throughout the entire lesion and around the base. If an ice ball does not appear, either the treatment time was not long enough or the foam tipped applicators were not completely saturated. The treatment will need to be repeated if an ice ball does not appear after application.

5. 

   The frozen lesion will need to thaw naturally for a minimum of 40 seconds. Premature warming of cells will minimize the effectiveness of the freeze, and the procedure will need to be repeated. Do not touch the lesion for a least 40 seconds after treatment.

6. 
   Dispose of applicator when all treatments per patient are complete. Do not use on multiple patients.

After the first treatment, assess if multiple Freeze/Thaw treatments are necessary. Occasionally, large, thick or calloused lesions (especially plantar warts) may require more than one Freeze/Thaw treatment per visit. With time and experience you will gain confidence as to which lesions will need multiple treatments.

Provide patient with after-care procedures in the "Patient Information" section of this instructional manual and in the Patient Instructions Tear Pad provided, and schedule a follow up visit in 10-14 days to assess results and determine if retreatment is necessary.

Recommended Freeze/ Thaw Times by Lesion

Skin Thickness: The freezing time should be shorter in treating lesions on thin skin and somewhat longer in treating lesions on thicker skin. With experience you will soon be able to estimate precise freezing times in order to achieve a minimal blister reaction. If ever in doubt when treating a benign skin lesion, always under treat rather than over treat, since you can always refreeze the under-treated lesion 1-2 weeks later. A two or three second spray time may be adequate for very thin skin. One or two additional seconds of spray time may be needed on very thick skin such as the sole of the foot. Also when treating lesions on very thick skin, superficial debriding of the lesion prior to freezing has been recommended by some physicians. On thick skin (especially with large plantar warts) a double or occasionally even triple freeze-thaw cycle should be used to increase the destructive effects of the cryogenic agent.

Treatable Lesions: Cool Renewal® should be used on benign, superficial skin lesions. Any lesion should be biopsied prior to treatment if the diagnosis is uncertain or there is suspicion of any cancer. Follow recommendations according to skin thickness above, whether a light freeze for superficial lesions or whether longer or multiple freezes are appropriate. Under-freeze if in doubt and re-evaluate in two weeks. The table below provides recommended freeze times for the most commonly treated lesion types.

Most Commonly Treated Lesions	Freeze Time Range*
Verruca Vulgaris (common warts)	30-40 seconds
Verruca Plantaris (plantar warts)	35-40 seconds
Actinic Keratosis (non-facial)	30-40 seconds
Actinic Keratosis (facial)	15-20 seconds
Achrochordon (skin tags)	25-35 seconds
Molluscum Contagiosum	20-30 seconds
Age Spots (non-facial)	25-35 seconds
Age Spots (facial)	15-20 seconds
Seborrheic (keratosis)	30-40 seconds

*** Remember to reduce treatment time by 10-15 seconds in thin skin areas, such as genitals.**

The freeze times provided in the chart above are only recommendations. When using cryosurgery, achieving maximum results will develop over time with practice and familiarity with the freeze/thaw procedures and results. Physicians/medical professionals and patients must work together and share the responsibility of proper use and desired results.

The frozen lesion will need to thaw naturally for a minimum of 40 seconds. Premature warming of the cells will minimize the effectiveness of the freeze, and the procedure may need to be repeated.

After the first treatment, assess if multiple Freeze/Thaw treatments are necessary. Occasionally, large, thick or calloused lesions (especially plantar warts) may require more than one Freeze/Thaw treatment per visit. With time and experience you will gain confidence as to which lesions will need multiple treatments. Schedule a follow up visit in 10-14 days to assess results and determine if retreatment is necessary.

Warning: Do not use on irritated or infected skin. Do not use on bleeding, open or breached lesions. Do not treat lesions if cancer is suspected. If there is doubt that a lesion is benign, lesion should first be biopsied.

Tips for Treatments

- Let your patients know what to expect. Inform them not to move during the procedure. As with all cryosurgery, there will be an initial sting or burning/cooling sensation for 3-10 seconds, usually followed by a dull, numbing pain, if any pain at all. This will decrease the patient's likeliness to move during the procedure. Pre-Treatment use of topical anesthetic cream, anesthetic spray or injectable anesthetic is advisable if patient is sensitive or overly anxious.
- When using the plastic funnels:
  - Be sure to firmly hold the cone in place during the entire procedure to prevent leakage.
  - Use GENTLE pressure on the trigger to avoid "blasting" and wasting the cryogen.
  - Spray into the side wall of the funnel rather than directly onto the skin to avoid splatter.
  - In the instance of an over treatment, use a foam tipped applicator to absorb excess cryogen inside of funnel.
  - You will gain confidence in the amount of cryogen needed with practice and experience. Using light trigger pressure will help control the amount of cryogen applied to each lesion. The amount of cryogen needed for each treatment will vary depending on the size and thickness of the lesion being treated. Larger, thicker lesions will have a longer freeze time than smaller, more superficial lesions, and will require a heavier application of cryogen. Thin skin lesions usually require less cryogen. Be sure to monitor the ice ball thaw time for maximum results. Always under-treat versus over-treat. The lesion may always be treated again in 1-2 weeks.
  - The largest size funnel may be inverted to treat mosaic lesions approximately 25mm in size, or larger lesions may be treated in sections using the largest funnel.
- When using foam tipped applicators:
  - For maximum coldness, be sure to saturate the foam tip until the tip drips at least 1 time.
  - Be sure to hold the applicator in place CONTINUOUSLY for the suggested freeze time. Dabbing or removing the applicator during the freeze time may reduce the effectiveness of the freeze.
  - Larger applicators may stay cold long enough to treat multiple lesions without additional saturation. Be sure that you achieve an ice ball with each treatment. If no ice ball appears, ignore the treatment and repeat with a fully saturated applicator.
- Allow lesions to thaw naturally. Rushing the thaw phase may reduce the effectiveness of the freeze.
- Thick and calloused lesions, such as plantar warts, can be debrided before treatment. Do not debride to the point of bleeding.
- The Ballooning Technique can be used to treat areas with extreme blood flow and blood vessels. Prior to treatment, the area can be "ballooned" with lidocaine to increase the effectiveness of the freeze by raising the lesion, constricting blood vessels, and allowing the cryogen to freeze deeper. This technique should be reserved for physicians who are experienced in cryosurgery and used with caution, as it intensifies the freeze.
- Application of salicylic acid after treatment is optional after the complete thawing of the last freeze/thaw cycle, but is not required with Cool Renewal®. Type of salicylic acid, dosage and frequency should be determined by physician. Patient should follow physician instructions for applications at home.

Tips for Treatments (Cont.)

- For genital lesions, remember that these are very thin skin areas. The spray and freeze times in the areas should be shorter for these areas (15-30 seconds) than for the thicker areas of the body (30-40 seconds).
- Be sure the patient is positioned where the cryogen can accumulate inside the funnel directly on top of the lesion. If the cryogen is spilling back out of the larger end onto the floor, the patient will need to be repositioned or foam tipped applicators may be used. Always keep the funnel perpendicular to the ground to allow for accumulation of cryogen inside the funnel. Never remove the funnel until all of the cryogen has completely evaporated. For first time users, raw meat may be used to simulate the freezing of tissue.
- On the cellular level, most of the permanent destructive effects from freezing occur during the thaw phase. If you see that you have inadvertently frozen adjacent normal tissue primarily from leakage beneath the funnel (because of patient movement, etc.) or had too much cryogen on the foam applicator tip, you can touch this area with your finger or the palm of your hand causing rapid rewarming. This significantly reduces the chances that some normal tissue will ultimately slough off and often only mild temporary erythema (redness) occurs.
- Depth of Freeze (DF) is the maximum depth of frozen tissue, "ice ball", under the center of the lesion. Lateral Spread of Freeze (LSF) is the minimal lateral extension of the "ice ball" peripheral to the area of application. When a flat surface is cooled evenly by cryospray, the depth of freeze is approximately equal to the lateral spread of freeze and is independent of the size of the treated area. The levels of cold within the tissue (tissue isotherms) vary with the rate of cooling; this freeze time is important in estimating ultimate tissue destruction. The faster the freeze, the deeper the destruction.

Practice Freezing Lesions Using Disposable Plastic Funnels:

Choose the 5mm funnel. Be sure to firmly depress the funnel onto the practice surface (wax, raw meat, or Applicator Practice Pad provided in your Kit) to prevent leakage of the cryogen. Gently pull the trigger. A white spray will appear. The most efficient method (maximizing the use of the freezing agent) is dripping the cryogen into the funnel until at least 1/8" to 1/4" (3mm) of cryogen accumulates and begins to bubble. This should take 3 to 6 seconds. Lightly spraying a fine mist into the funnel is also effective. Moderate or hard spraying only increases splattering and wastes the cryogen. Although occasional splattering has no dire consequences, except around the eyes, it can be annoying and irritating to both the physician and patient. **Foam Tipped Applicators are recommended for treating lesions on the head, face and neck.**

After accumulating at least 1/8" - 1/4" of cryogen in funnel cease spraying and allow the cryogenic agent to evaporate (boil off). Continue to hold the cone firmly on the practice surface to prevent leakage.

You can hear and see the cryogenic agent evaporate. This evaporation usually takes 30-40 seconds. If the evaporation time is significantly less than 40 seconds on a patient, you probably under-froze the lesion and may need a second or even a third freeze-thaw cycle.

After the cryogen has completely evaporated, you may remove the funnel. You should see a concentric white ice ball. This is the beginning of the thaw stage which lasts a minimum of 40 seconds. Take care not to touch the ice ball during the thaw period since the heat withdrawn from your finger will shorten the thaw time and reduce the effectiveness of the freeze. It is thought that on the cellular level, most of the permanent destructive effects from freezing occur during the thaw stage. A thaw time significantly less than 40 seconds can be due to inadequate freezing or a patient with "hot" hands or feet.

Practice Freezing Lesions Using Foam Tipped Applicators:

Foam Tipped Applicators are available in multiple sizes (Small round, Small pointed, Medium round, Medium pointed, Large & Extra-Large).Choose a Foam Applicator. To saturate the foam before freezing, hold the canister in one hand and the foam applicator in the other hand. Very gently pull the trigger and spray onto foam tip until the foam tip is saturated – You will know the foam is saturated when it starts dripping. Wait 10-15 seconds before application. Then place the foam directly on the practice surface (raw meat, wax or Applicator Practice Pad) and hold firmly for 15-40 seconds. After the freeze time has been completed, remove the applicator. The "lesion" or practice treatment site should appear white. The thaw time should be a minimum of 40 seconds. If the thaw time is considerably less than 40 seconds, the "lesion" has not been frozen properly and may need another freeze-thaw cycle. Just as with isolation funnels, do not touch or allow the patient or the patient's clothing to touch the lesion prior to thawing.

Practicing with various sized isolation funnels and foam tipped applicators using raw steak or wax should give a realistic feel of the freezing process. The Applicator Practice Pad provided in the Cool Renewal® Kit may also be used in place of raw meat or wax.

Practice Freezing Lesions Using Skin Tag Tweezers:

To saturate the foam before freezing, hold the canister in one hand and the foam applicator in the other hand. Very gently pull the trigger and spray onto both foam pads until the foam tip is saturated – You will know the foam is saturated when it starts dripping. Wait 10-15 seconds before application. If using raw meat or wax, use the tweezers to squeeze the surface, and hold firmly for 15-40 seconds. If using the Applicator Practice Pad provided in the Cool Renewal® Kit, fold the pad in half with the black rubber side facing outward, and squeeze the pad from both sides, simulating squeezing of a skin tag. The "lesion" or practice treatment site should appear white. The thaw time should be about 40 seconds. If the thaw time is considerably less than 40 seconds, the "lesion" has not been frozen properly and may need another freeze-thaw cycle. Just as with isolation funnels and foam tipped applicators, do not touch or allow the patient or the patient's clothing to touch the lesion prior to thawing.

Frequently Asked Questions

1. How many lesions can I treat with a canister of Cool Renewal®?

   The actual number of treatments per canister will vary depending on the size of the lesions treated, and the amount of cryogen used for each treatment. The advertised number of treatments per canister is based on using the medium rounded foam tipped applicator.

2. What is the recommended freeze time for Cool Renewal®?

   Freeze times will vary depending on the lesion location and size. Thinner skin areas, such as the face and genitals, will require a shorter freeze time than thicker skin areas, such as the feet.

3. What is the shelf life of Cool Renewal® and how do I store it?

   Cool Renewal does not evaporate and has a minimum shelf life of 1 year from the opening date. Canisters should be stored at room temperature away from sunlight or heat, preferably in the magnetized box provided for convenience.

4. What are the proper codes for reimbursement?

   See the CPT Coding section of this manual, or consult with your local medical billing representative. Reimbursements will vary from state to state as well as carrier to carrier.

5. When to use Foam Tipped Applicators vs. Plastic Funnels?

   It's up to you! Both applicators will produce the same results, although Isolation funnels should NEVER be used on the head, face, or anywhere a tight seal is not achievable.

6. Tips for Perfecting Foam Tipped Applicator Freezing Technique

   To ensure that the cryogen reaches the ultimate temperature after saturating the applicator, wait approximately 10-15 seconds before applying it to the lesion. Ice crystals should begin to appear. Be sure not to "dab" the applicator, but to apply it continuously for the suggested freeze time.

7. Why is my canister only spraying air?

   It's likely that your canister is empty and it is time to reorder! Try turning your trigger nozzle 360° (this will relocate the tube inside the canister). This is common when the canister is reaching the point of emptiness, as well as sputtering when tilted at a 45° angle when using Isolation Funnels. If your canister feels full but is only spraying air, please contact customer service for additional troubleshooting.

   Cool Renewal, LLC- 615.844.0132, info@cool-renewal.com

8. I lost my Extender Tube that inserts into the nozzle. Now what?

   Open spray without an extender tube can cause damage to healthy tissue. Additional extender tubes may be purchased individually **(Item CR-TUBE, pack of 10)**, or with a Cool Renewal® Complete Cryosurgical Kit or Replacement Canister.

9. What happens if the canister is dropped and the nozzle is broken?

   If you drop your canister, be sure to inspect the nozzle and canister before use. If the nozzle appears to be broken or is not working properly, contact Cool Renewal® Customer Service for a replacement. A broken canister must be returned for a replacement.

Patient Instructions after Treatment

Always tell your patients what to expect and how to take care of the lesions post treatment. The aftercare is just as important as the treatment itself. A Patient Instruction Tear Pad has been provided. Please give a copy to each of you patients after treatment with Cool Renewal, LLC.

- Today your physician used a freezing agent to destroy your skin lesion. This technique is common in treating a variety of skin lesions.
- Most patients experience little or no pain with cryosurgery, but if you do, consult with your physician about taking aspirin (adults only), ibuprofen or acetaminophen.
- If a large or painful blister becomes present, your physician may drain the blister to relieve pain.
- With a successful treatment, the treated area may blister, turn a dark brown or black, or form a crust/scab within a few hours or days. This is normal and part of the destruction and healing process.
- No dressing is necessary immediately after freezing. If the bullous formation begins draining in 2-3 days, a small Telfa® pad covering might be beneficial for 1-2 days. Be sure to leave the lesion uncovered at night as healing will be faster.
- Cleansing the lesion with water or peroxide on a Q-tip™ might be beneficial during the 3-5 days after treatment.
- If a scab or crust forms, it is recommended that you not pull or irritate the scab, and let it slough naturally. This should take approximately 7-14 days, depending on the size, location and your personal healing ability.
- It's ok to shower, but try to keep the treated area as dry as possible.
- No bandage is necessary, but may be used to protect the healing lesion from injury if desired. Try to leave the area open to air as often as possible to promote the crusting/scabbing process.
- Once the scab has sloughed, the new skin may be red, sensitive, or even itch as it is healing. Do not bandage, irritate, or apply medications after the scab falls off. Normal skin color should return over a few weeks or months.
- Contact your physician if you have further questions or concerns.

Replacement Components & Purchasing

For replacement components, or to order an entire kit, please contact your preferred medical or veterinary supply distributor. A complete list of our distributors can be found on our website at www.cool-renewal.com.

If your preferred supply distributor does not offer Cool Renewal®, we are happy to contact them about adding us to their current product line, or you may purchase directly from us through our website at www.cool-renewal.com.

Cool Renewal® Complete Cryosurgery Kit- Item #CR-K
Includes:
- (2) Cool Renewal® canisters of cryogen
- Extender Tube (2)
- Instructions for Use
- Mixed pack of 60 disposable Foam Tipped Applicators
  - 20 Small, round and pointed tips
  - 20 Medium, round and pointed tips
  - 20 Large/Extra Large, round tips
- Mixed Pack of 50 disposable plastic funnels
  - 10 (5mm)
  - 10 (8mm)
  - 10 (12mm)
  - 10 (14mm)
  - 10 (16mm)
- Skin Tag Tweezers (10 pack)
- Patient Instructions Tear Pad
- Applicator Practice Pad

Cool Renewal® Replacement Canisters ONLY- Item #CR-RC
Includes:

- (2) Cool Renewal® canisters of cryogen
- Extender Tube (2)
- Instructions for Use

Foam Tipped Applicators (all double tipped)
- Small, round and pointed (60/pack) Item #FTA-S
- Medium, round and pointed (60/pack) Item #FTA-M
- Large/Extra Large, both ends round (60/pack) Item # FTA-LXL
- Assorted Pack- 20 Small, 20 Medium, 20 Large/Extra Large Item #FTA-A

Disposable Plastic Isolation Funnels
- 5mm, pack of 50- Item # CR-F5
- 8mm, pack of 50- Item # CR-F8
- 12mm, pack of 50- Item # CR-F12
- 14mm, pack of 50- Item # CR-F14
- 16mm, pack of 50- Item # CR-F16
- Assorted Pack, 10 of each size, 50 total- Item # CR-FA

Disposable Skin Tag Tweezers: Item # CR-TWZR20 (Pat. No. US D749,729 S)
- (20/Pack)

Extender Tubes: Item # CR-TUBE
- (10/Pack)

Patient Instructions Tear Pad: Item # CR-PITP

Applicator Practice Pad: Item # CR-APP

CPT Coding & Reimbursements

CODE	DESCRIPTION
17000	Benign Lesions: Destruction of 1 Benign Lesion
17003	Benign Lesions: Destruction of 2-15 benign lesions
17004	Benign Lesions: Destruction of 15 or more benign lesions
17110	Warts & Molluscum: Destruction of 1-14 flat warts, molluscum, or milia
17111	Warts & Molluscum: Destruction of 15 or more flat warts, molluscum, or milia.
11200	Skin Tags: Destruction of 1-15 skin tags
11201	Skin Tags: Destruction of each additional 10 skin tags
46916	Anal Lesions: Simple destruction of anal lesion, SIMPLE
46924	Anal Lesions: Extensive destruction of anal lesion,) EXTENSIVE
54056	Penile Lesions: Simple destruction of penile lesion, SIMPLE
54065	Penile Lesions: Extensive destruction of penile lesion, EXTENSIVE
56501	Vulva Lesions: Destruction of Vulva Lesions- SIMPLE
56515	Vulva Lesions: Destruction of Vulva Lesions- EXTENSIVE
57061	Vaginal Lesions: destruction of lesion, SIMPLE
57065	Vaginal Lesions: destruction of lesion, EXTENSIVE

For billing and reimbursements, it is recommended that the following American Medical Association CPT® Codes are used. The reporting procedures for these codes may vary from carrier to carrier, and are ultimately left up to the physician to interpret.

http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding- billing-insurance/cpt.page

Works Cited

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